1021276

PATENT SPECIFICATION

NO DRAWINGS

1021276

Date of Application and filing Complete Specification: May 27, 1963.

No. 21110/63.

Complete Specification Published: March 2, 1966.

Index at acceptance:—A5 B(1D, 1F, 1N, 1P, 1S)

Int. Cl.:—A 61 k 3/00

COMPLETE SPECIFICATION

Medicinal Composition and method for the Treatment of Acne and Acne Sequelae

We, ROSE BALLINE SAPERSTEIN, of 643 South Wilton Place, Los Angeles 5, California, United States of America, and WERNER KOCH STIEFEL, of Oak Hill, New York, United States of America, both citizens of the United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a medicinal composition and method for the treatment of acne and acne sequelae by a new technique which utilizes long-term, continuous superficial graded abrasion during the active phases of the acne.

The skin consists of two layers, the dermis or true skin and the epidermis. The outer layer, the epidermis, continually renews itself by growth from beneath and the invisible shedding of the outer cornified dead cells. The epidermis itself is divided into five layers, from the innermost stratum germinativum to the outer corneum. As the cells progress outwardly they change in character and, by the time the cell reaches the stratum corneum, they are dead and are altered in chemical composition. The chemical composition of the outer horny layer (stratum corneum) is largely keratin and the entire cycle is usually termed the "keratinization cycle". The keratin cell residues of the stratum corneum are flattened and overlap in a shingle-like arrangement which is flexible and yet protective in nature.

The skin areas of the face, neck, chest and back are equipped with numerous hair follicles. These exist in both men and women, whether or not hair actually grows from the follicles. These hair follicles are equipped with oil glands which secrete an oily material, known as sebum, into the follicles.

Acne or acne vulgaris is a disease of the hair follicles and of the oil secretion process, in which the oil (sebum) secretion exceeds the oil excretion. The precise etiology is unknown, except that it is known to be triggered by the hormonal changes taking place in the body at puberty, due to emotional stresses and strains, and possibly other factors.

In acne, the hair follicles become plugged. The precise nature of the plug is known only approximately. It consists of a mixture of dead keritinized cells and sebum, with the sebum acting as a cementing matrix. The plug is the familiar "blackhead". The sebaceous gland down in the follicle continues to operate, pumping sebum into the plugged follicle. Presently, a pimple is formed and occasionally bacterial invasion takes place, resulting in the formation of a pustule. A third complication which often occurs in untreated acne is a horizontal bursting of the follicular wall, causing lateral spread of the sebaceous material beneath the skin surface.

Acne can be a severe condition. It causes the skin to be unsightly at the time of life when the young person is likely to be most sensitive to personal appearance. This unsightly appearance of the skin tends to place the person under an emotional strain which can be detrimental to the individual even after the acne itself has been cured. Furthermore, its more serious forms frequently leave the skin permanently scarred, with serious detriment to the individual's appearance.

One method for the treatment of acne has been the exposure of the skin to X-ray radiation. It has recently been realized that exposure to X-ray radiation should be avoided, except when absolutely necessary. Consequently, this treatment for acne is less widely used than it was formerly.

Another treatment has been the application of keratolytic or keratin-dissolving agents, such as salicyclic acid, to the surface of the skin. The use of chemical keratolytics is necessarily a delayed-reaction type of procedure, with the result that over-treatment occurs quite often. The result of such over-treatment can be quite severe.

It has heretofore been recognized that the majority of people afflicted with acne appear to be improved during the summer months, following exposure to more intense sunlight, and that relapses occur with the disappearance of the suntan. The improvement following repeated and prolonged exposure to sunlight is thought to be due largely to increased superficial cutaneous desquamation which may be minute or obvious, and to the restoration of consequent patency to the pilosebaceous follicles. However, efforts to treat acne by exposure to the radiation of mercury vapour quartz lamps alone have not been uniformly successful, and it is not usually practical for the patient to make the required daily visits to the physician.

Recently, the use of synthetic detergents, with or without added keratoplastic and keratolytic agents, has been popular. While helpful in some cases, they are often extremely drying and fail to accomplish the mild, continuous and prolonged desquamation which is caused by exposure to strong sunlight and which appears to be essential for sustained improvement of acne.

Topically applied abrasives and keratolytic materials have also been used for the treatment of acne. Heretofore, such treatment has not been long continued, because the very properties which cause the combination of an abrasive and a keratolytic agent to be therapeutic also causes them to be irritating to the skin.

The research on which this invention is based initially demonstrated that the use of various abrasives in the treatment of acne caused intense scaling and redness of the skin in the case of many patients, although it was found that when the erythema subsided, the number of comedones (blackheads) was reduced and the skin appeared smoother. This research subsequently resulted in the development of the composition in accordance with this invention, which is therapeutically capable of maintaining patency of the pilosebaceous follicles but which creates desquamation mild enough to be cosmetically compatible with daily living and which minimizes sequelie (pitting).

The composition in accordance with this invention is a paste which comprises a non-oleaginous detergent base having dispersed therein an inorganic abrasive which has a hardness greater than 7 as measured by Moh's Index, is non-piezo-electric and has a particle size distribution within the range of 125 microns to 710 microns. Preferably, at least 70%, by weight, of the abrasive particles have a particle size within the range of 175 microns to 600 microns.

It has been found that the abrasive contained in this composition must have a hardness greater than 7 as measured by Moh's Index to be effective in the treatment of acne. This is believed to be due to the fact that the yield point of the sharp corners of a softer abrasive is too low for the abrasive particles to gouge the skin sufficiently to dig out the keratinous plugs. Also, softer particles tend to destroy each other by fragmentation.

The particle size of the abrasive is equally important. The individual particles should not be large enough to cause an actual scratching or cutting of the skin and, therefore, should not be large relative to the thickness of the skin. It is impossible for the individual abrasive particle to plough a groove as deep as the particle's diameter since, if it is embedded in the skin so deeply, the fingers would have nothing to push against. The depth to which the particle penetrates the skin depends upon the applied pressure but it can be estimated that 50% to 75% of the particle is left protruding during the use of the composition, while making a groove having a cross-section of 25% to 50% of the size of the particle.

The thickness of the epidermis varies enormously in different individuals and in different areas of the body. It may range in thickness from 150 to 500 microns and often falls outside that range. However, the composition may contain particles as large as 710 microns since the applied pressure is the controlling factor in the depth of the groove cut by the particles. The patient will not scrub much harder than the pain threshold in using the composition, particularly when cautioned not to do so.

The size of the pore openings is the governing factor which controls the minimum size of the abrasive particles used in our composition, since it is undesirable to drive the particles down into the pores. The diameter of hair is a guide to the maximum size of the follicular openings. Various authors have reported hair diameters of 100 microns, 170 microns, and 260 microns, and hair is well known to vary widely from fine to coarse. However, it is impossible to drive a particle into a follicle already filled by a hair shaft. When the follicles have no hair or only rudimentary or lanugo hair, they have smaller openings due to the stricturing effect of normal skin tension. We have found that we may include particles as small as 125 microns in diameter in our composition without detrimental effects from the particles being driven into the hair follicles.

The research on which this invention is based has also demonstrated that it is desirable for the abrasive used in each of the compositions used in the successive stages of the treatment of acne to include particles of different sizes. While this is an empirically observed clinical observation, it is believed to result from the combination of an effective ploughing action of the larger particles on the keratin plugs already formed and of an effective scrubbing action by the smaller particles, which removes the outer dead keratin cells and tends and prevent the future formation of plugs. The larger particles are less effective

than the smaller particles in the removal of the dead keratin cells, since they make grooves relatively far apart. In addition, the smaller particles have a levelling action between the grooves left by the larger particles.

Further, the research on which this invention is based has demonstrated that in the course of continued treatment of acne by the use of our abrasive compositions, the skin becomes increasingly tolerant or resistant to the desquamation caused by the treatment, permitting the use of successively more highly abrasive compositions. It has been shown that in the treatment of a given case of acne, it is desirable to use a series of compositions differing in degree of abrasiveness in which the proportion of the course to the fine particles of the abrasive and the proportion of the abrasive to the nonoleaginous base are both successively increased for use in successive stages of the treatment.

We have found that an abrasive having particle sizes within the ranges given by Table I is entirely satisfactory for use in our composition.

TABLE I

Particle Size Distribution of Non-piezo-electric Abrasive

Size Range in Microns	Per Cent by Wt. of the Total Abrasive
125 - 149	0 - 2
149 - 177	4 - 8
177 - 250	20 - 40
250 - 420	40 - 60
420 - 590	10 - 25
590 - 710	0 - 4

Further, we have found that abrasives used in a series of compositions of increasing abrasiveness, for the multi-stage treatment of acne, may, for example, have particle size distributions within the ranges given by Table II.

TABLE II

Particle Size Distribution of Non-piezo-electric Abrasives for Use in a Coordinated Series of Compositions

Size Range in Microns	Mild Abrasiveness	Medium Abrasiveness	Strong Abrasiveness
125 - 149	1.0% - 2.0% by Wt.	0.9% - 1.5% by Wt.	0.8% - 1.2% by Wt.
149 - 177	5.4% - 8.0% " "	5.8% - 6.5% " "	5.7% - 6.2% " "
177 - 250	22.0% - 28.0% " "	23.4% - 24.0% " "	22.5% - 23.1% " "
250 - 420	41.3% - 50.0% " "	41.5% - 50.2% " "	41.5% - 50.2% " "
420 - 590	16.8% - 19.0% " "	19.4% - 20.0% " "	20.5% - 21.1% " "
590 - 710	2.8% - 3.6% " "	3.0% - 3.6% " "	3.4% - 4.1% " "

The ratio of the abrasive to the nonoleaginous base in our composition can be varied over a wide range. The composition may contain as little as 10%, by weight, of the abrasive particles or as much as the nonoleaginous base will carry and still retain its pasty nature, which we have found to be about 80%, by weight. Thus, the composition may contain from 10% to 80% by weight, of the abrasive particles, and we prefer to include an amount of the abrasive in the composition within the range of 30% to 70%, by weight.

As noted hereinbefore, the abrasiveness of our compositions can be varied both by the selection of the abrasive used in terms of its particle size distribution and by the variation in the ratio of the abrasive to the nonoleaginous base in the composition. In the preparation of a series of compositions for the multi stage treatment of acne we prefer to vary both factors, and we have found that it is essential to vary the ratio of the abrasive to the base in the composition to secure definite and effective differences in the abrasiveness of the compositions. Table III gives ranges of the proportions of the abrasive and the base for such a series of our abrasive compositions.

TABLE III

Ratios of Abrasive to Non-Oleaginous Base in a Coordinated Series of Compositions in Parts by Weight

	Abrasive	Non-oleaginous Base
Mild Abrasiveness	10 - 44	95 - 66
Medium abrasiveness	44 - 58	66 - 42
Strong abrasiveness	58 - 70	42 - 30

It will, of course, be understood that a coordinated series of compositions can be prepared using any desired number of different compositions of graded abrasiveness by varying both the particle size distribution of the abrasive used in the different compositions as illustrated by Table II and the ratio of the abrasive to the non-oleaginous base contained in the compositions. The amount of the abrasive used in the compositions may be varied within the range of 10% to 80%, by weight.

The non-oleaginous detergent base which forms the matrix in which the abrasive particles are suspended acts as a carrier for the abrasive particles and a cleanser for the skin. It must have the consistency of a paste and be cosmetically acceptable. It comprises essentially a combination of a surface active agent and a solvent therefor in amounts which give it the desired paste consistency. The solvent may be water or it may be an organic liquid which is non-poisonous and non-irritating to the skin. It may contain a plurality of different surface active agents. The surface active agent or agents contained in the non-oleaginous base may be cationic, anionic or non-ionic in character. Although the exact composition of the non-oleaginous base is not critical, provided that it has the physical characteristics of a paste, we have found that the combination of water, an ordinary soap, and an alkali metal salt of a sulfated fatty alcohol is particularly satisfactory for use in this composition. By the term "an ordinary soap" we mean a salt of a fatty acid containing at least eleven carbon atoms or a mixture of such fatty acids. Thus, the non-oleaginous base may comprise a mixture of an alkali metal or alkanolamine salt of a sulfated higher fatty alcohol, such as the triethanolamine, lithium, sodium or potassium salt of lauryl sulfate, stearyl sulfate, oleyl sulfate, or the sulfate of a fatty alcohol mixture, and an alkali metal salt of a higher fatty acid, such as the lithium, sodium or potassium salt of lauric acid, myristic acid, stearic acid, oleic acid, or a mixture of such acids.

The proportion of water included in the aqueous, non-oleaginous base of the composition in accordance with this invention will depend upon the particular surface active agent or agents which are used therein but, with any particular surface active agent or combination of surface active agents, the water should be present in an amount which gives the base the physical consistency of a paste and which permits the surface active agent or combination of surface-active agents to function as a detergent and emulsifying agent for the oily sebum of the skin.

As indicated by the fact that we have characterized our base by the term "non-oleaginous", it should not be oily in nature. Thus, it should not have the over-all characteristics of an oily ointment or of a cold cream. It may, however, contain a minor quantity of a fatty material and we may include, as an emollient, a minor proportion of lanolin in the composition. Other types of emollients may be included in the composition, such as polyethylene glycol dioleate, polyethylene glycol mono-oleate, polyethylene glycol dilaurate, polyethylene glycol monolaurate and glycerine. It may also contain a mixture of different chemical types of emollients. Thus, we may include a mixture of lanolin, polyethylene glycol dioleate and glycerine in the composition.

The composition in accordance with this invention may also contain an antiseptic and bactericidal material, such as hexachlorophene, 3,4,4' - trichlorocarbanilide and bithionol U.S.P. We may use any one or a combination of the recognized bactericides. Hexachlorophene is entirely suitable for this purpose. The composition may also contain in addition to the non-oleaginous base and the abrasive, powdered solids other than the abrasive hereinbefore described. Thus, it may contain inert pigments to give it colour and it may contain a minor amount of bentonite or a similar material to improve its consistency. In connection with the use of bentonite in the composition, it may be noted that when included in this composition, it does not function as an effective abrasive, despite the fact that it is generally recognized as an abrasive and polishing agent, and is widely used for these purposes in other types of compositions.

In the foregoing, it has been specified that the abrasive which is used in this composition is non-piezo-electric, i.e. incapable of pro-

ducing a piezo-electric current. Various piezo-electric powdered alkaline earth carbonates, granites, porcelains, various silicates and silicon dioxide, having particle sizes within a suitable range, have been used in compositions effective in the treatment of acne. However, non-piezo-electrical abrasives are used in the composition of this invention from the standpoint of avoiding any possibility of the development of granuloma as a result of the use of the composition. We have found that fused, synthetic aluminum oxide which is non-piezo-electric in nature is a clinically satisfactory abrasive for use in our composition.

Heretofore, it has been recognized that granuloma formation is caused by the deep traumatic implantation in the skin of a crystal having piezo-electric properties and the proper crystal size. Silicon dioxide, for example, is known to cause the rather severe skin condition known as silicon granuloma. This action of the silicon dioxide has been traced to its piezo-electrical characteristic. This action of silicon dioxide in causing silicon granuloma upon deep implantation in the skin has created a prejudice against products containing silicon dioxide, even though their use is unlikely to cause any implantation of the silicon dioxide in the skin. Our composition avoids the possibility of causing granuloma by the use of an abrasive having no piezo-electrical characteristics and avoids the prejudice against products containing silicon dioxide.

Table IV gives the screen analysis of a series of three fused, synthetic aluminium oxide abrasives which we have used in a series of three compositions according to the invention which are coordinated for the treatment of a given case of acne, and which have been successfully used in such treatment.

TABLE IV

Screen Analyses of a Coordinated Series of Aluminum Oxide Abrasives

Size Range in Microns	Ex. No. 1 Fine	Ex. No. 2 Medium	Ex. No. 3 Coarse
125 - 149	1.5%, by Wt.	1.2%, by Wt.	1.0%, by Wt.
149 - 177	6.7%, „ „	6.2%, „ „	5.9%, „ „
177 - 250	25.0%, „ „	23.7%, „ „	22.8%, „ „
250 - 420	45.7%, „ „	45.9%, „ „	45.8%, „ „
420 - 590	17.9%, „ „	19.7%, „ „	20.8%, „ „
590 - 710	3.2%, „ „	3.3%, „ „	3.7%, „ „

The abrasive illustrated by example 1 is suitable for use in a mildly abrasive composition while that of Example 2 is suitable for use in a composition of intermediate or medium abrasiveness. That of Example 3 is suitable for use in a more highly abrasive composition. A comparison of the screen analysis of these three abrasives shows that they differ primarily in the relative percentages of particles in the 177—250 micron and in the 420—590 micron particle size ranges, with the percentages of the smaller particles decreasing step-wise and the percentages of the larger particles increasing step-wise.

The same non-oleaginous base may be used in these compositions of different degrees of abrasiveness in a coordinated series of our compositions. Example 4 illustrates a non-oleaginous base which we have successfully used in a coordinated series of our compositions.

EXAMPLE 4

Non-Oleaginous Base Composition

Sodium lauryl sulfate	12.0%, by Wt.
Sodium laurate	3.5%, „ „
Sodium myristate	3.5%, „ „
Sodium stearate	7.0%, „ „
Lanolin	0.5%, „ „
Polyethylene glycol	10.1%, „ „
Glycerine	2.8%, „ „
Water	60.6%, „ „
	100.0%

It will be noted that Example 4 includes a mixture of three different ordinary soaps, i.e. sodium laurate, sodium myristate and sodium stearate with a synthetic surface active agent, i.e. sodium lauryl sulfate. Further, it will be noted that it contains three different emollients, i.e. lanolin, polyethylene glycol and glycerine. Although lanolin is a fat, the percentage in which it is used is far too low to destroy the non-oleaginous character of the composition.

The composition of Example 4 is prepared by blending the detergents and emollients in the water to produce a smooth, creamy paste. The percentage of water given (60.6%, by weight) is adequate for this purpose with the surface active agents used. However, the percentage of water required to give a desirable paste consistency to the composition will vary with different mixtures of surface active agents and even with different proportions of the four surface active agents of Example 4. Thus, an increase in the amount of sodium stearate, with a corresponding decrease in the amount of sodium laurate used in the composition, requires an increase in the amount of water used in the composition.

Examples 5, 6 and 7 given in Table V illustrate a coordinated series of compositions in accordance with this invention in which the abrasives illustrated by Examples 1, 2 and 3, respectively, are used in admixture with the non-oleaginous base illustrated by Example 4.

TABLE V

A Coordinated Series of Compositions for the Treatment of a Given Case of Acne

	Ex. No. 5 % by wt.	Ex. No. 6 % by wt.	Ex. No. 7 % by wt.
Base composition of Ex. 4	56.5	43.3	31.0
Hexachloroprene	1.0	1.0	1.0
Bentonite	5.3	4.3	3.3
Abrasive of Ex. 1	37.2	—	—
Abrasive of Ex. 2	—	51.4	—
Abrasive of Ex. 3	—	—	64.7
Total—	100.0	100.0	100.0

The compositions of Table V are prepared by thoroughly blending the ingredients listed for each example to produce a composition in which the abrasive and the bentonite are uniformly suspended in the base.

The composition of Example 5 is a mild composition which is adapted for use in the initial stages of the treatment of a case of acne. The composition of Example 6 is a composition of intermediate or medium abrasiveness adapted for the intermediate treatment of a case of acne which has been treated by the use of the composition of Example 5. The composition of Example 7 is a relatively highly abrasive composition which is intended for use in the final stages of the treatment of a case of acne which has been treated first by the use of the composition of Example 5 and then by the use of the composition of Example 6.

A comparison of the compositions of Examples 5, 6 and 7 shows that they are progressively more abrasive, in the order named, because of two progressive variations in their compositions. One of these variations is the use of abrasives having progressively larger proportions of larger size particles which has been discussed hereinbefore with reference to Table IV. The second of these progressive variations is in the relative proportions of the non-oleaginous base and of the abrasive included in the composition. It will be noted that the percentage of the oleaginous base is progressively decreased, while the percentage of the abrasive is progressively increased, from the composition of Example 5, through that of Example 6 to that of Example 7.

While the foregoing Examples 5, 6 and 7 illustrate coordinated series of compositions in accordance with our invention, it will be appreciated that many intermediate compositions may be prepared to produce a coordinated series of compositions in which the gradation from one composition to the next is less severe than in case of the illustrated series. Extensive clinical testing of these compositions has shown that with some cases of acne it is desirable to use a more extensive and more gently graded series of compositions than that illustrated by Examples 5 to 7, inclusive.

From a manufacturing and merchandising standpoint, it is desirable to minimize the number of different compositions in a coordinated series. We have found that this can be done, for example, by supplying the physician and the patient with a series of three graded compositions such as those illustrated by Examples 5-6, inclusive, together

with a non-oleaginous base composition such as that illustrated by Example 4, to which, if desired, a bactericide may be added. Thus, for example, we may add about one per cent, by weight, hexachlorophene to the composition of Example 4.

A base composition, such as that illustrated by Example 4, enables the physician, or even the patient, to prepare compositions which are less abrasive than any one of a series of coordinated compositions, such as those illustrated by Examples 5-7, inclusive, by merely diluting the composition with the proper quantity of the base composition. Also, the base composition is useful, as such, since it is well adapted for the removal of excess oil from the skin.

In the treatment of acne by the use of the compositions in accordance with this invention, on the patient's first visit the physician takes a complete history of any previous treatments, any contact allergies, the course of the development of the acne, the oiliness of the skin, and other relevant facts. If the patient has had no regular cleaning routine, a base composition containing no abrasive, such as that illustrated by Example 4, is first used to thoroughly clean the skin. The mildest abrasive composition, such as that illustrated by Example 5, of a coordinated series of compositions is then prescribed. The patient is instructed to use the composition on the skin while it is dry, scrubbing well therewith with a rotary motion for approximately ten counts, and finally removing the composition from the skin by the use of a wash cloth and hot water. This routine should require no more than two or three minutes. The patient is instructed to repeat this routine three times daily until dryness, redness and disquamation occur. It is explained to the patient that these reactions are desirable for good therapeutic results and that, only if the skin becomes irritated, should the routine be interrupted for a day or so. After an interruption of the routine because of skin irritation, it has been observed that no further scaling of the skin occurs when the routine is resumed, despite the previous irritation.

After a proper interval, the physician may again see the patient to assure that the routine is being properly followed. Resistant blackheads may be expressed at that time. After this routine is followed for a period of three or four weeks, the skin appears smoother and the comedones are significantly reduced in number. There even may be a return of some oiliness of the skin.

The physician may then prescribe the use of a somewhat more abrasive composition of the graded series and the patient instructed to follow the same routine as with the original composition. The composition in accordance with this invention which is prescribed at this point may be, for example, that illustrated by Example 6, or it may be a somewhat milder composition which is more abrasive than the original composition, such as a composition prepared by mixing the composition of Example 6 with a calculated quantity of a non-oleaginous base, such as that illustrated by Example 4. The exact increase in the abrasiveness of the abrasive composition is determined by the physician in view of the nature of the patient's skin, its reaction to the first abrasive composition and the condition of the acne. In the use of this second grade of the abrasive composition, the same sequence of events occurs as those resulting from the use of the first composition, i.e. erythema, dryness and scaling, which again stop, despite the continued use of this grade of the abrasion paste. At the end of this sequence of events, most of the comedones have disappeared, the skin is smoother in appearance and the previous pitting is less noticeable.

The foregoing is then repeated, using a composition in accordance with this invention which has an increased abrasive strength over that last used, when the skin still appears oily after the foregoing phase of the treatment. Each patient appears to reach an equilibrium, depending upon the skin type and the acne type. The optimum therapeutic effect is attained when the skin remains free of comedones and minutely flaky. The stages of the treatment using progressively stronger abrasive compositions are continued until this optimum therapeutic effect is achieved.

The use of progressively more abrasive compositions in accordance with this invention during the continued treatment of acne is not always indicated. The abrasiveness of the composition used should be decreased when too much desquamation occurs, such as with increased exposure to sunlight or with maturity when the skin is naturally drier than it is during adolescence. On the other hand, the physician can prescribe compositions of increased abrasive strength when the skin becomes increasingly oily. It has been observed that patients soon learn to control the degree of abrasion indicated by the condition of their skin and keep compositions in accordance with this invention of different abrasive strengths at home for use as the condition of their skin requires.

The majority of patients improve appreciably after six weeks of continuous superficial graded abrasion by the use of the compositions in accordance with this invention. The need for self manipulation of the facial lesions and pimples then disappear almost entirely since there are fewer lesions and the routine of the treatment apparently replaces the emotional need to scrutinize and express each lesion.

After the optimum therapeutic effect is attained, the progressive increase in the abra-

siveness of the abrasive composition used is terminated but the treatment is continued with that abrasiveness which has been reached, with the objective of keeping the sebum washed off the skin, while the patency f the sebaceous ducts is maintained. As patients stay well, some become careless about their routine and omit this treatment, with the result that the oiliness and comedones soon reappear. A resumption of the treatment again corrects the condition.

This technique of continuous superficial graded abrasion by the use of the compositions in accordance with this invention may be used with all patients with acne vulgaris, regardless of other treatments used, which may include Vitamin A, antiseptic creams, lotions, vaccines, antibiotics and evacuation of fluctuant lesions, and even when X-rays are simultaneously given. When improvement is accomplished, the adjunct treatments are discontinued but the abrasion treatment is continued.

The continued superficial abrasion by the use of the composition in accordance with this invention permits young patients to outgrow the disease with little or no scarring. These compositions have been used with patients in the late twenties or thirties who were afflicted with pits and scars, but who were not anxious for wire brush surgery or were not good candidates for such surgery. Six months of graded abrasion by the use of these compositions has resulted in excellent subjective and objective improvement with such patients. It has also been found that if a mild abrasion treatment by the use of the compositions in accordance with this invention is begun after erythema subsides following wire brush surgery, the oiliness and small milial cysts do not appear.

No ill effects have been observed clinically as a result of the use of the composition of this invention with many acne patients. No changes in pigmentation after prolonged use were seen in Negro or Caucasian skins. The contra indications to the use of these compositions are few. When there are a number of superficial venules and/or telangiectasia present in the skin, harsh abrasion is naturally avoided.

In the foregoing, the use of the compositions in accordance with this invention in the treatment of acne and acne sequelae has been discussed in detail. The use of these compositions is not limited to the treatment of acne. We have found that the continuous, superficial abrasion technique using these compositions is also effective in the treatment of hyperkeratosis palmaris and plantaris due to tinea. Also, it may be beneficial in yet unexplained skin problems.

WHAT WE CLAIM IS:

1. A therapeutic composition for application to the skin having the physical characteristics of a paste, characterized in that it is a suspension of an inorganic abrasive, preferably a fused synthetic aluminium oxide, having a hardness greater than 7, as measured by Moh's Index, being non-piezo-electric and having a particle size distribution within the range of 125 microns to 710 microns, in a non-oleaginous paste comprising a surface active agent and a solvent therefor, which is non-poisonous and non-irritating to the skin, for example, water.

2. A therapeutic composition according to claim 1, characterized in that at least 70%, by weight, of the abrasive particles have a particle size of 175 microns to 600 microns.

3. A therapeutic composition according to claim 1 or 2, characterised in that it contains from 10% to 80%, by weight of said abrasive.

4. A therapeutic composition according to any of claims 1 to 3, characterised in that the surface active agent includes at least one alkali metal salt of a fatty acid containing at least eleven carbon atoms and an alkali metal salt of a sulfated fatty alcohol.

5. A therapeutic composition according to claim 4, characterised in that the alkali metal fatty acid salt is sodium laurate, sodium myristate, and/or sodium stearate, and the alkali metal salt of a sulfated fatty alcohol is sodium lauryl sulfate.

6. A therapeutic composition according to any of claims 1 to 5, characterised in that the paste also comprises at least one emollient, for example lanolin, polyethylene glycol or glycerine.

7. A therapeutic composition according to any of claims 1 to 6, characterised in that the paste also comprises a bactericide, for example hexachlorophene.

8. A therapeutic composition according to any of claims 1 to 7, characterised in that a minor proportion of bentonite is also suspended in the paste.

9. A co-ordinated series of therapeutic compositions according to any of the proceding claims, for use in the multi-stage treatment of acne, wherein the compositions in said series differ from one another in their degree of abrasiveness, and wherein the proportion of the coarse to the fine particles of the abrasive and the proportion of the abrasive to the non-oleaginous base are both successively increased for use in said series.

10. A co-ordinated series of therapeutic compositions according to claim 9, characterised in that it consists of a mild abrasive composition comprising from 10 to 44 parts by weight, of a fused synthetic aluminium oxide abrasive having from 1.0% to 2.0%, by weight, of its particles within the particle size range of 125 microns to 149 microns, from 5.4% to 8.0% by weight, within the range of 149 microns to 177 microns, from

22.0% to 28.0%, by weight, within the range of 177 microns to 250 microns, from 41.3%, to 50.0%, by weight, within the range of 250 microns to 420 microns, from 16.8% t 19.0%, by weight, within the range of 420 microns to 590 microns, and from 2.8% to 3.6%, by weight, within the range of 590 microns to 710 microns and from 95 to 66 parts, by weight, of a non-oleaginous base; a medium abrasive composition comprising from 44 to 58 parts, by weight, of a fused synthetic aluminium oxide abrasive having from 0.9% to 1.5%, by weight, of its particles within the particle size range of 125 microns to 149 microns, from 5.8% to 6.5%, by weight, within the range of 149 microns to 177 microns, from 23.4% to 24.0%, by weight, within the range of 177 microns to 250 microns, from 41.5% to 50.2%, by weight, within the range of 250 microns to 420 microns, from 19.4% to 20.0%, by weight, within the range of 420 microns to 590 microns, and from 3.0% to 3.6%, by weight, within the range of 590 microns to 710 microns and from 66 to 42 parts, by weight, of a non-oleaginous base; and a coarse abrasive composition comprising from 58 to 70 parts, by weight, of a fused synthetic aluminium oxide abrasive having from 0.8% to 1.2%, by weight, of its particles within the particle size range of 125 microns to 149 microns, from 5.7% to 6.2%, by weight, within the range of 149 microns to 177 microns, from 22.5% to 23.1%, by weight, within the range of 177 microns to 250 microns from 41.5% to 50.2%, by weight, within the range of 250 microns to 420 microns, from 20.5% to 21.1%, by weight, within the range of 420 microns to 590 microns, and from 3.4% to 4.1%, by weight, within the range of 590 microns to 710 microns, and from 42 to 30 parts, by weight, of a non-oleaginous base.

11. A therapeutic composition substantially as hereinbefore described with reference to any one of Examples 5, 6 and 7.

12. A co-ordinated series of therapeutic compositions substantially as hereinbefore described with reference to Examples 5, 6 and 7.

13. A therapeutic composition comprising a suspension of an inorganic abrasive substantially as hereinbefore described with reference to any one of Examples 1 to 3 in a non-oleaginous paste substantially as hereinbefore described with reference to Example 4.

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Leamington Spa: Printed for Her Majesty's Stationery Office, by the Courier Press (Leamington) Ltd.—1966. Published by the Patent Office, 25 Southampton Buildings, London, W.C.2, from which copies may be obtained.